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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,835	06/23/2005	Kohji Kawahara	10936-88	2192

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	**PAPER NUMBER**
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,835	KAWAHARA ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/27/2007, 9/6/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III and the species of antiallergic agent and further the election of ketotifen fumarate in the reply filed on November 3, 2008 is acknowledged. Upon examination, the election was expanded to prednisolone (steroids) which is a known antiallergy/antiinflammotory drug (see Bellman U.S. Pat. 5811417).

Status of Application

2. Applicant has elected Group III and the species of antiallergic agent and further the election of ketotifen fumarate in response to restriction requirement and for the examination. The election was expanded to prednisolone (steroids) which is a known antiallergy/anti-inflammatory drug.

Due to restriction, based on election of Group III, claims 1-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim 20 is present for examination at this time.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially" in claim 20 is a relative term which

renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term is subjective as it is relative and comparative with no specific or clear recitation on what amount, percent, or degree of improvement is considered “substantially”. It does not allow one of skill in the art to ascertain the metes and bounds of the invention.

5. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “without being administered through a systemic blood flow" is unclear as the transdermal flow of drug through the skin will pass through the blood vessels and some amount of the drug will enter the blood circulation which is the systemic circulation. This is further confusing as the specification on Pages 8-9 recited that the drug is not being administered through a systemic blood flow which as addressed above is going to occur to some degree due to the transdermal transfer, but goes on to recite that it does not intend to exclude the fact that part of the remedy (drug) is delivered to the ophthalmic tissue through the systemic blood flow which is contrary to what is recited previously in the specification and the claims. It does not allow one of skill in the art to ascertain the metes and bounds of the claims. For purposes of prosecution, the recitation of the exclusion of the systemic transfer is not given weight as a method of administering a composition with the named components in the same

mode of administration will produce the same results which will result in some transfer to the blood circulation.

6. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what ocular conditions are being treated as the claim as written encompasses all ocular conditions, but not all ocular diseases are treatable such as Leber's congenital amaurosis or LHON. Leber's congenital amaurosis is chromosomally linked autosomal disorder where there is abnormal development and lack of the photoreceptors and blindness ensues. There is no treatment other than symptomatic and support as the patient is unable to form the rods and cons needed for slight. Presentation occurs typically at birth or soon after (see Moss). Leber's hereditary optic neuropathy (LHON) is a mitochondrially-inherited condition where the optic nerve undergoes neuropathy related to changes in the mitochondrial DNA. Presentation is typically men in their twenties and thirties but symptoms can happen at any age to both men and women. The mitochondria are unable to provide adequate energy to the cells and the optic nerve and retina become damaged or necrosis. There is no current conventional treatment for Leber's hereditary optic neuropathy (see Newman). It is unclear what ocular conditions are being treated and does not allow one of skill in the art to ascertain the metes and bounds of the claims. For purposes of prosecution, the claim is view for the treatment of allergic response.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Tojo et al. (WO 01/26648).

It is noted that U.S. Pat. 7052714 will be used as the translation for WO 01/26648 and all references are to the U.S. Patent.

Tojo et al. teaches transdermal preparations comprising an adhesive with a drug (plaster) with a release membrane, and a lining film (support). A drug exemplified and claimed is prednisolone. The patch can be applied to any desired body surface including the eyelid (see full document, specifically, Abstract, Col. 2 line 10-68, Col. 5 line 27-col. 7 line 40, col. 13 line 55- Col. 15 line 20, claim 7-10, 13-14, 16). It is noted that the claim reciting a method for transferring a remedy(drug) for ophthalmic diseases to an ophthalmic topical tissue comprising applying a transdermal drug delivery system comprising a plaster and a support, to the skin surface of an eyelid. However, transfer of the drug inherently occurs when a composition with the recited components (such as transdermal formulation) is applied to the cited mode of administration (applied to the skin of an eyelid). In fact, drug transfer is inherent to transdermal formulations by the nature of the art.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kissel (U.S. Pat. 5593686) in view of Trimming et al. (U.S. Pat. Pub. 2001/0006968) in view of Lerner et al. (WO 97/18855).

Kissel et al. teaches the use of a transdermal patch for the administration of active agents including ketotifen with a reservoir and a support (see full document).

Kissel does not expressly teach placement on the eyelid.

Timming et al. teaches that ketotifen (e.g. ketotifen fumarate) is useful for the treatment of allergic conjunctivitis, such as seasonal allergic conjunctivitis (see full document).

Lerner teaches that the skin of the eyelid has a resistance lower than that on the rest of the skin surface (Page 37 line 38- Page 38 line 1).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the ketotifen patch on the eyelid for its known use, as suggested by Timming and Lerner, and produce the instant invention. It would have been obvious to one of skill in the art as ketotifen is known in the art to be used for allergic conditions including allergic conjunctivitis and as the transdermal patch provides consistent delivery in the transdermal for as addressed by Kissel, it would be obvious to

use the transdermal patch for allergic conjunctivitis and place the patch as close to the site as possible particular as it is taught by Lerner that the skin surface over the eyelid has less resistance that the rest of the skin of the body to provide not only direct deliver but more effective delivery as there is better penetration from the lower resistance.

One of ordinary skill in the art would have been motivated to do this because it is desirable to provide better delivery of a known composition for a known treatment with greater efficacy.

It is noted that the transfer of a remedy (drug) intrinsically occurs when a composition with the recited components (such as transdermal formulation) is applied to the cited mode of administration (applied to the skin of an eyelid). In fact, drug transfer is intrinsic to transdermal formulations by the nature of the art.

Double Patenting

11. Claim 20 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-7, 11, 23, 25-27 of copending Application No. 10/569772 in view of Tojo et al. (WO 01/26648).

The claims of the conflicting application are drawn to the application of a muscarinic receptor agonist in a base matrix (acrylic, silicone, rubber adhesive) to the skin surface of the eyelid to promote lacrimal fluid secretion which is more specific than the generic instant claim of applying a drug (remedy) in a plaster (base matrix) to the skin surface of the eyelid for treatment of a condition.

The conflicting claims do not recite a support. However, as taught by Tojo et al. it is obvious to add a support (lining film) to the base matrix as part of a transdermal

delivery system to improve adhesion. As a result, the instant claim is obvious over the copending claims and encompasses the specific conflicting claims.

This is a provisional obviousness-type double patenting rejection.

Conclusion

12. Claim 20 is rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612